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Paul D. Golian

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February 6, 2007

Date

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

**CONFIRMATION NO: 2857** 

MARTHA LI

INTERNATIONAL APPLICATION NO:

PCT/US0424424

U.S. APPLICATION NO: 10/567,867

371 DATE: 07/29/2004

FOR: BIOMARKERS OF CYCLIN-

DEPENDENT KINASE MODULATION

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

Applicant believes this paper is being filed before the mailing date of a first Office Action on the merits, and so under 37 C.F.R. §1.97(b)(3) no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-3880.

In accordance with 37 C.F.R. §1.56, Applicant wishes to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Pursuant to the OG Notice of August 5, 2003 for U.S. national applications filed after June 30, 2003, the requirement for submitting a copy of each cited U.S. patent and each cited U.S. patent application publication is waived and, accordingly, copies of the U.S. patent and U.S. patent publications are not submitted. Copies of foreign patent documents and non-patent literature are enclosed.

publications are not submitted. Copies of foreign patent documents and non-patent literature are enclosed.

Some of the listed references were cited in a search report in a corresponding PCT International application. A copy of the search report is also enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000

Paul D. Golian Attorney for Applicant Reg. No. 42,591

Phone: (609) 252-4091

Date: February 6, 2007

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	Application Number	10/567867				
	Filing Date	07/29/2004				
	First Named Inventor	MARTHA LI				
	Art Unit					
	Examiner Name					
	Attorney Docket Number	D0310 US - PCT				

	U.S.	PATENT DOC	UMENTS	
Cite No.	Document Number	Publication date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AA	5,569,588	10/29/1996	Ashby et al.	
AB	6,040,321	03/21/2000	Kim et al.	
AC	6,214,852	04/10/2001	Kim et al.	
AD	6,262,096	07/17/2001	Kim et al.	
AE	6,515,004	02/04/2003	Misra et al.	
AF	6,521,759	02/18/2003	Kim et al.	
AG	6,783,961	08/31/2004	Edwards et al.	
	U.S. PATENT APPLI	CATION PUBL	ICATIONS DOCUME	
Cite No.	Document Number	Publication date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AH	US 2004/0253606 A1	12/16/2004	Aziz et al.	
	AA AB AC AD AE AF AG Cite No.	Cite No.         Document Number           AA         5,569,588           AB         6,040,321           AC         6,214,852           AD         6,262,096           AE         6,515,004           AF         6,521,759           AG         6,783,961           U.S. PATENT APPLI           Cite No.         Document Number	Cite No.         Document Number         Publication date MM-DD-YYYY           AA         5,569,588         10/29/1996           AB         6,040,321         03/21/2000           AC         6,214,852         04/10/2001           AD         6,262,096         07/17/2001           AE         6,515,004         02/04/2003           AF         6,521,759         02/18/2003           AG         6,783,961         08/31/2004             U.S. PATENT APPLICATION PUBL           Cite No.         Document Number         Publication date MM-DD-YYYY	No.   Document Number   MM-DD-YYYY   Applicant of Cited Document

-	FOREIGN PATENT DOCUMENTS							
Examiner Initials	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Check box if English language translation is attached		
	Al	WO2001/66719 A1	09/13/2001	PCT	ABSTRACT ONLY, abs, SEQ ID NO:s 2071 and 2072			

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 6	09: Draw a line through citation if not in conformance and not

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or form 1449/PTO	COMPL	ETE IF KNOWN
	Application Number	10/567867
INFORMATION DISCLOSURE	Filing Date	07/29/2004
	First Named Inventor	MARTHA LI
STATEMENT BY APPLICANT(S)	Art Unit	
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**D0310 US PCT** 

Attorney Docket Number

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article(when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Check box if English language Translation is attached
-	2AA	Akama, Y. et al., "Frequent amplification of the Cyclin E Gene in Human Gastric Carcinomas", Jpn. J. Cancer Res., Vol. 86, pp. 617-621 (1995)	
•	2AB	Blanchard, A. et al., "Sequence to array: Probing the genome's secrets", Nature Biotechnology, Vol. 14, pp. 1649 (1996)	
	2AC	Catzavelos, C. et al., "Decreased levels of the cell-cycle inhibitor p27 Kip1 protein: Prognostic implications in primary breast cancer", Nature Medicine, Vol. 3(2), pp. 227-230 (1997)	
	2AD	Courjal, F. et al., "Cyclin gene amplification and overexpression in brease and ovarian cancers: evidence for the selection of Cyclin D1 in breast and Cyclin E in ovarian tumors", Int. J. Cancer, Vol. 69, pp. 247-253 (1996)	
	2AE	Draetta, G. et al., "Activation of <i>cdc2</i> Protein Kinase during Mitosis in Human Cells: Cell Cycle-Dependent Phosphorylation and Subunit Rearrangement", Cell, Vol. 54, pp. 17-26 (1988)	
	2AF	Dynlacht, B. et al., "Specific Regulation of E2F Family Members by Cyclin- Dependent Kinases", Molecular and Cellular Biology, Vol. 17(7), pp. 3867- 3875 (1997)	
	2AG	Fredersdorf, S. et al., "High level expression of p27 <sup>kip1</sup> and cyclin D1 in some human breast cancer cells: Inverse correlation between the expression of p27 <sup>kip1</sup> and degree of malignancy in human breast and colorectal cancers", PNAS, Vol. 94, pp.6380-6385 (1997)	
	2AH	Gould, Kathleen, "Cyclin-dependent protein kinases", Protein Kinases, pp. 149-166 (1994)	
	2AI	Harper, J. Wade, "Cyclin Dependent Kinase Inhibitors, Cancer Surveys, Vol. 29, pp. 91-107 (1997)	
	2AJ	Keyomarsi, K. et al., "Cyclin E, a Potential Prognostic Marker for Breast Cancer", Cancer Research, Vol. 54, pp. 380-385 (1994)	
	2AK	King, R. et al., "How Proteolysis Drives the Cell Cycle", Science, Vol. 274, pp. 1652-1659 (1996)	
	2AL	Kitahara, K. et al., "Concurrent amplification of Cyclin E and CDK2 Genes", Int. J. Cancer, Vol. 62, pp. 25-28 (1995)	

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Substitute for form 1449/PTO				COMPLETE IF KNOWN		
					Application Number	10/567867
	INFORMATION	SIG NC	SCLOSURE		Filing Date	07/29/2004
					First Named Inventor	MARTHA LI
	STATEMENT	「BY AI	PLIC	CANT(S)	Art Unit	
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Sheet	3		F	2	Attorney Docket Number	D0310 US PCT

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article(when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Check box if English language Translation is attached
•	3AA	Li, J. et al., "Nuclear localization of cyclin B1 mediates its biological activity and is regulated by phosphorylation", PNAS, Vol. 94, pp. 502-507 (1997)	
-	3AB	Lockhart, D. et al., "Expression monitoring by hybridization to high-density oligonucleotide arrays", Nature Biotechnology, Vol. 14, pp. 1675-1680 (1996)	
	3AC	Morgan, David, "Principles of CDK regulation", Nature, Vol. 374, pp. 131-134 (1995)	
	3AD	Nigg, Erich, "Cellular substrates of p34 <sup>cdc2</sup> and its companion cyclin-dependent kinases", Trends in Cell Biology, Vol. 3, pp. 296-301 (1993)	
	3AE	Ookata, K. et al., "MAP4 Is the in Vivo Substrate for CDC2 Kinase in HeLa Cells: Identification of an M-Phase Specific and a Cell Cycle-Independent Phosphorylation Site in MAP4", Biochemistry, Vol. 36, pp. 15873-15883 (1997)	
	3AF	Pines, J. et al., "Isolation of a Human Cyclin cDNA: Evidence for Cyclin mRNA and Protein Regulation in the Cell Cycle and for Interaction with p34 <sup>cdc2</sup> ", Cell, Vol. 58, pp. 833-846 (1989)	
	3AG	Porter, P. et al., "Expression of cell-cycle regulators p27 <sup>Kip1</sup> and cyclin E, alone and in combination, correlate with survival in young breast cancer patients", Nature Medicine, Vol. 3(2), pp. 222-225 (1997)	
	3AH	Rickert, P. et al., "Cyclin C/CDK8 is a novel CTD kinase associated with RNA polymerase II", Oncogene, Vol. 12, pp. 2631-2640 (1996)	·
	3AI	Schena, M. et al., "Quantitative Monitoring of Gene Expression Patterns with a Complementary DNA Microarray", Science, Vol. 270, pp. 467-470 (1995)	
	3AJ	Tan, P. et al., "The Cell Cycle Inhibitor p27 Is an Independent Prognostic Marker in Small (T <sub>1a,b</sub> ) Invasive Breast Carcinomas", Cancer Research, Vol. 57, pp. 1259-1263 (1997)	
	3AK	Wang, A. et al., "Different expression patterns of cyclins A, D1 and E in human colorectal cancer", J. Cancer Res Clin Oncol, Vol. 122, pp. 122-126 (1996)	
	3AL	Van den Heuvel, S. et al.," Distinct Roles for Cyclin-Dependent Kinases in Cell Cycle Control", Science, Vol. 262, pp. 2050-2054 (1993)	

Examiner	Date	
Signature	Considered	